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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,008	03/24/2004	Roger Cady	57294.019	5678

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,008	CADY, ROGER	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *10-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-9 and 14-16 in the response filed December 3, 2004 is acknowledged. The traversal is on the ground(s) that a reference (U.S. Patent 6,113,915) is cited to indicate the claimed product can be used in a materially different process than the process claimed, where the reference teaches the intrathecal or intraspinal administration of botulinum toxin for the treatment of pain, while the products claimed are specific to transdermal application of botulinum toxin; and the method and product claims are both classified in the same class, which suggests the identified inventions have not acquired separate search. This is not found persuasive because the traversal is not on the grounds that the inventions are not independent and distinct, rather, the traversal is on the grounds that the burden of search is not undue. As such restriction is proper if two or more claimed inventions are either independent **or** distinct. See MPEP 803. The claimed product (e.g., topical solution comprising botulinum toxin, saline and a suitable base) is not different from the solution of botulinum toxin containing saline and a pharmaceutical carrier as indicated in the patent (see column 13, line 66-column 14, line 5), thus the restriction is proper between the product and the process of use when the claimed product can be used in a materially different process, i.e., intrathecal or intraspinal administration of botulinum toxin for the treatment of pain. Furthermore, coexamination of the additional group would require search of the article or solution containing botulinum toxin. Therefore, coexamination of this invention would require an additional burden of search.

The restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the invention is not

coextensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-9 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 1-9 and 14-16 are indefinite as to what effective amount of botulinum toxin type A would do in the method of treatment. Claims 2-9 and 15 are rejected for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

4. Claim 1-6, 9, 14 and 15 are indefinite because of the use of the term "sensory neuron related disorder". The term cited renders the claim indefinite, it is unclear what disease the sensory neuron related disorder refers to since the specification does not define the term. Claims 2-6, 9 and 15 are rejected for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

5. Claim 9 is indefinite as to how electrophoresis is applied in the step of transdermal application of botulinum toxin type A.

6. Claim 16 recites the limitation "the topical cream" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-3, 5-7, 9, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Donovan (US 2004/0009180, filed July 11, 2002).

Donovan teaches a pharmaceutical composition containing a botulinum toxin (e.g., botulinum toxin type A) is used to treat several types of disorders associated with neurotransmitter release (e.g., migraine, fibromyalgia, pain from muscle spasm) by topical administration of the composition (paragraph [0066]; Examples 3, 4 and 6; claims 1, 2, 7), wherein the botulinum toxin can be lyophilized, reconstituted with saline or water, and an

enhancing agent such as alcohol or lipid can be added to the composition (paragraphs [0069]-[0073]; claim 3); the composition containing the botulinum toxin and the enhancing agent is provided in a trandermal patch having an adhesive layer, a reservoir holding the botulinum toxin and an exterior surface (paragraphs [0074]-[0075]; claims 5, 6); and the trandermal patch may include iontophoresis which can help deliver the botulinum toxin to a subdermal target site by passing electrical current across the patch (paragraph [0083]; claim 9). Since the reference teaches the same method steps in the method of treating a sensory neuron related disorder, e.g., transdermal administration of botulinum toxin type A to a patient, it would be expected that botulinum toxin type A inhibits the release of neuropeptides such as calcitonin gene-related peptide (claims 14-15).

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK
January 19, 2005